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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/090,268  | 03/04/2002  | Robert Wyckoff       | 2001-8050-RA        | 4134             |
| 30184   | 7590        | 04/10/2006           | EXAMINER            |                  |
| MYERS & KAPLAN, INTELLECTUAL PROPERTY LAW, L.L.C.<br>1899 POWERS FERRY ROAD<br>SUITE 310<br>ATLANTA, GA 30339 |             |                      | RAGONESE, ANDREA M  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3743                |                  |

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 10/090,268             |  | WYCKOFF, ROBERT     |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Andrea M. Ragonese     |  | 3743                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date: <u>20060403</u>                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: <u>10/27/2005</u>   | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2005 has been entered.

***Response to Amendment***

2. It appears that on December 2, 2005, with the RCE, form PTO/SB/30, Applicant has submitted a copy of an Amendment/Reply to be considered by the Examiner, even though Applicant requested that the previously submitted Amendment, filed October 3, 2005, be considered. Since the amendment filed with the RCE is a duplicate copy of the Amendment, filed October 3, 2005, the Examiner has considered hereinafter only the merits of the Amendment, filed October 3, 2005.

3. The amendment filed on October 3, 2005 has been entered. Examiner acknowledges that **claims 1, 5, 8, 12 and 17** have been amended. Subsequently, **claims 1-20** are under consideration, while **claims 21-24** have been withdrawn from further consideration.

***Drawings***

4. The drawings were received on October 3, 2005. These drawings are not acceptable because they must be labeled in the top margin as either "Replacement Sheet" pursuant to 37 CFR 1.121(d).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures.

If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Response to Arguments***

5. Applicant's arguments with respect to original **claims 1-20** have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 1-20** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. See MPEP § 608.04. Specifically, **claims 1 and 17** now recite(s) the claim limitation(s): elements that are "extending substantially coextensive," "portions...spaced apart from the neck of the user" and regions of "a generally negative pressure" (emphasis added by the Examiner). The originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention(s) at the time the application was filed. There is no specific recitation or support for these newly recited limitations; and therefore, the subject matter added to **claims 1 and 17** are considered new matter and must be canceled from the claim(s).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-5 and 10-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Scarberry et al. (US 5,343,878). Scarberry et al. discloses a device **60** for wear on the neck of a user which is fully capable of maintaining air pathway clearance (see Abstract), as shown in Figure 4, comprising:

a support member **62**, said support member **62** having an inner surface, an outer surface and a peripheral edge;

securing means **66**, said securing means **66** carried by said support member **62** and said securing means **66** enabling retention of said support member **62** on the neck of the user;

retention means **70**, said retention means **70** enabling retention of said securing means **66** relative to said support member **62**;

a seal **72**, said seal **72** secured to and extending substantially coextensive with said peripheral edge of said inner surface of said support member **62**—wherein Applicant has not sufficiently provided adequate written description to support this definition of the term “coextensive”, the Examiner has drawn the definition of “coextensive” from the *Merriam-Webster Online Dictionary* as “having the same spatial or temporal scope or boundaries” (emphasis added by Examiner), thus meeting the claim limitation since seal **72** is within “the same spatial boundaries” of the peripheral edge of the inner surface of support member **62**—and said seal **72** enabling substantially airtight positioning of said support member **62** against the neck of the user, said seal **72** protruding laterally—wherein Applicant has not sufficiently provided adequate written description to support this definition of the term “laterally”, the

Examiner has drawn the definition of "lateral" from the *Merriam-Webster Online Dictionary* as "of or relating to the side; situated on, directed toward, or coming from the side" (emphasis added by Examiner), thus meeting the claim limitation since seal **72** is situated in a relationship with "the side" and is "coming from the side" of the inner surface of the support **62**—beyond said inner surface of said support member **62** such that portions of said inner surface of said support member **62** are spaced apart from the neck of the user;

an air compartment **74** that is defined by an area bound by said inner surface of said support member **62**, said seal **72** and the neck of the user; and

at least one valve **78**, said valve **78** carried by said support member **62**, wherein said valve **78** is fully capable of enabling the exit of air from said air compartment between said inner surface of said support member **62** and the neck of the user during expansion of the neck during exhalation;

wherein the device is fully capable of creating a generally negative pressure in said air compartment during subsequent inhalation such that the negative pressure on the exterior surface of the neck holds open air pathways of the user.

10. **Claims 17, 18 and 20** are rejected under 35 U.S.C. 102(b) as being anticipated by Scarberry et al. (US 5,343,878). Scarberry et al. discloses a sleep apnea device **60** for use on the neck of a user (see Abstract), as shown in Figure 4, comprising:

a neck cuff **62** having a generally arcuate shape, a concave surface and a peripheral edge;

at least one strap **66** carried by the neck cuff **62**, said at least one strap **66** having at least one fastener **70** for securing the position of the neck cuff **62** on the neck of the user;

a gasket **72**, said gasket **72** secured to and extending substantially coextensive with said peripheral edge of said concave surface of said neck cuff **62**—wherein Applicant has not sufficiently provided adequate written description to support this definition of the term “coextensive”, the Examiner has drawn the definition of “coextensive” from the *Merriam-Webster Online Dictionary* as “having the same spatial or temporal scope or boundaries” (emphasis added by Examiner), thus meeting the claim limitation since seal **72** is within “the same spatial boundaries” of the peripheral edge of the concave surface of neck cuff **62**—and said gasket **72** protruding beyond said concave surface of said neck cuff **62** such that portions of said concave surface of said neck cuff **62** are spaced apart from the neck of the user, and said gasket **72** defining a sealed region **74** between said concave surface of said neck cuff **62** and the neck of the user;

at least one vacuum regulator **78**, said vacuum regulator **78** carried by said neck cuff **62**, wherein said vacuum regulator **78** permits a unidirectional flow of air from said sealed region **74**;

wherein the unidirectional flow of air from said sealed region **74** is fully capable of creating a generally negative pressure in said sealed region **74** such that the negative pressure on the neck holds open air pathways of the user.



11. The Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **claims 1 and 17**, Applicant recites, "wherein a generally negative pressure is created..." Scarberry et al. discloses an apparatus **60** in which the claimed functional limitation(s) can inherently be performed since the apparatus **60** of Scarberry et al. utilizes a seal **72** and a valve **78** in combination with a vacuum connection **76** that is capable of creating negative pressure in area **74**. This recitation is a statement of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner, the previously presented rejection is applied to **claims 1 and 17** based on the prior art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 6-9 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarberry et al. (US 5,343,878), as applied to **claim 1** above, in view of Calabrese (US 4,886,052). Scarberry et al. teaches an apparatus comprising all limitations recited in **claims 6-9 and 16**, but does not expressly disclose that the securing means includes both a strap and another attachment mechanism selected from the group consisting of a buckle, a snap, a clasp and a magnet or that the support member is formed of a plurality of linked segments.

At the time of the invention was made, all of these types of attachment mechanisms for linking together more than one support member segment were very well known in the art and prevalently used. Specifically, Calabrese teaches that "a strap fastener...prevents further expansion of slit **35**, and firmly secures front collar half **12'** to the contour of the patient's neck" (column 9, lines 39-54). However, Calabrese also teaches that "[those] skilled in the art will clearly recognize that any suitable fastening means such as an adjustable buckle, snaps or the like, can be utilized to perform the function" (column 9, lines 54-57). Buckles, snaps, clasps and magnets are all equivalents in the field of securement.

Therefore, it would have been obvious to one having ordinary skill in the art to use any one of these securement means as Applicant has done to firmly secure more than one support member segment together.

Moreover, Applicant has not asserted that the specific securement means or the plurality of linked segments recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a hook and loop fastener assembly attaching together two ends of a one-piece construction support member, thus the use of any other type of securement means or a multiple segmented support member lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any type of adjustable attachment mechanism that is capable of opening/sealing and closing/resealing a support member, whether it is constructed of one segment or more than one segment, around a patient's neck.

Therefore, it would have been obvious to modify the apparatus of Scarberry et al. by altering the securing means to be any one selected from the group of buckles, snaps, clasps and magnets and to secure more than one support member segment together because it is well known in the art to use these types of securing means in order to secure the multiple segments of a support apparatus to the neck of a patient.

15. **Claims 13-15 and 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarberry et al. (US 5,343,878), as applied to **claims 1 and 17** above, in view of Sackner (US 4,452,252). Scarberry et al. discloses an apparatus comprising all the

limitations recited in **claims 13-15** and **19**, with the exception of a data collection port and means for measuring performance.

However, the use of a data collection port and means for measuring performance was known at the time the invention was made. Specifically, Sackner teaches the use of device with a data collection port for analyzing "specific pulmonary events, such as snoring, coughing, apneas, swallows, etc." (column 2, line 60 through column 3, line 9).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Scarberry et al. by adding a measurement device with a data collection port because it is well known in the art, as taught by Sackner, to use such a device for monitoring a patient's vital signs in order to measure the performance of an apparatus.


### ***Conclusion***

16. Applicant should note that if any further amendment to the claims were to properly incorporate allowable subject into the claim language, thus placing this application in condition for allowance, withdrawn **claims 21-24**, drawn to an invention non-elected with traverse, should be canceled in order to expeditiously further prosecution of the instant application.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR   
April 3, 2006

